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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,361	09/11/2003	Manfred Bohn	02481.1580-02000	3001

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,361	BOHN ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/2/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 28-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 28-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 2, 2006 has been entered.

Terminal Disclaimer

The terminal disclaimer filed on August 2, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,352,686 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claim 48 recites a method for preventing psoriasis of nails, which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Evaluating enablement requires determining whether any undue experimentation is necessary for a skilled artisan to determine how to make and/or use the claimed invention. Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: 1) the breath of the claims; 2) the nature of the invention; 3) the state of the prior art; 4) the level of one of ordinary skill; 5) the level of predictability in the art; 6) the amount of direction provided by the inventor; 7) the existence of working examples; and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

1) The breath of claims: The scope of the claimed method extends to a total prevention of any possible occurrence of psoriasis of nails.

2) The nature of the invention: The claimed invention is directed to a topical application to nails of an "effective amount" of a varnish comprising clobetalsol propionate with no further limitations. The duration of the prophylactic treatment or dosage of the drug is not further defined in the claim.

3) The state of the prior art: The prior arts teach that psoriasis is a chronic relapsing symptom, and there is no teaching on total prevention of nail psoriasis. See, for example, Bernstein (US 4250164), col. 1, lines 6-7.

4) The level of predictability in the art: Whether a topical application of an anti-psoriasis agent would totally prevent psoriasis from ever occurring is highly unpredictable.

5) The amount of direction provided by the inventor: the only disclosure related to a preventive method is found on p. 7, lines 17-19 of the specification, which states, that the invention is suitable for prophylactic treatment against a possible recurrence of the symptom.

6) The existence of working examples: The specification provides no example of preventing nail psoriasis.

7) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The burden of enabling the prevention of a nail condition (i.e., the need for additional testing) would be greater than that of enabling a treatment, due to the need to screen those humans susceptible to such conditions.

In the instant case, the specification does not provide guidance as to how one skilled in the art would go about preventing those patients susceptible to nail psoriasis within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing the nail condition conditions among the population. The specification fails to enable "prevention", and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method for the prevention of nail psoriasis.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 28-36, 38, 40-45, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4250164) in view of Rossomando (US 4179304) and Fredriksson (US 3966924).

Bernstein teaches a method of treating nail psoriasis by applying onto the infected nail a lacquer composition comprising a glucocorticoid as a sole active ingredient. The reference teaches that fluocinolene acetonide, fluorandrenolide, triamcinolene acetonide, and betamethasone valerate have been used in topical formulation to treat psoriasis. See col. 1, line 19 – col. 2, line 5. Example 1 shows a nail polish composition comprising Valisone lotion (betamethasone valerate in isopropyl alcohol and carboxy vinyl polymer) and Revlon® clear nail polish. The method of using the composition is taught in Examples 2-4. See instant claims 48 and 49.

While Bernstein does not explicitly disclose the constituents of the Revlon nail polish, it is viewed that the Revlon product used in the Bernstein example contains the nail polish ingredients of the present invention of instant claims 1, 33-36, 38, and 40-45.

Rossomando teaches in col. 1, line 67 – col. 2, line 6, "a typical nail polish formulation as sold by Revlon, Inc., of New York has the following ingredients: butyl acetate, toluene, nitrocellulose, ethyl acetate, isopropyl alcohol, toluenesulfonamide/ formaldehyde resin, dibutyl phthalate, camphor . . . and malic acid." See instant claims 33-35 and 40-45. Rossomando also teaches that copolymers of alkyl acrylates and methacrylates are well known film-forming polymers for nail polish formulations. See col. 3, lines 17-20; instant claims 36 and 38.

Bernstein fails to teach clobetasol propionate, the glucocorticoid of instant claim 1, and the amount of the active ingredient as recited by applicants in claims 28 and 29.

Fredriksson teaches that clobetasol propionate and betamethasone valerate are art-recognized equivalents for treating psoriasis. The prior art invention is directed to a synergistic formulation comprising 5-fluorouacil and a halogenated corticosteroid composition, which include flurandrenolone acetonide, betamethasone valerate, fluocinolone acetonide, triamcinolone acetonide, and clobetasol propionate. See col. 1, line 57 – col. 2, line 16. See instant claims 1 and 30. The reference teaches using 0.01-5 % of the corticosteroid in a suitable vehicle. See instant claims 28, 29 and 32.

While the claim limitation of claim 31 requires at least 8 % by weight of glucocorticoid, examiner notes that differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is viewed that one or ordinary skill in the art would have modified the amount of the glucocorticoid with the motivation to make a strengthened anti-psoriasis formulation.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the Bernstein composition by substituting the glucocorticoids therein with clobetasol propionate as motivated by Fredriksson because the latter teaches that clobetasol propionate and betamethasone valerate are art-recognized

equivalents. Given the teaching of a nail polish comprising a glucocorticoid as a sole active ingredient, the skilled artisan would have had a reasonable expectation of successfully producing an anti-psoriatic nail polish that comprises clobetasol propionate as the sole active ingredient.

Claim 37, 39, 46, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein, Rossomando and Fredriksson as applied to claims 1, 28-36, 38, 40-45, 48 and 49 as above, and further in view of Bohn (US 5264206).

The combined references fail to teach the film-forming agent of instant claims 37-39 and the additives of instant claims 46 and 47.

Bohn teaches nail lacquer compositions to treat mycoses of nails. The reference teaches the film-forming agents of instant claims 36 and 38, which include polyvinyl acetate, copolymers of vinyl acetate, acrylic acid or crotonic acid or monoalkyl maleates. See col. 2, line 58 – col. 4, line 28. The copolymer of methyl vinyl ether and mono-n-butyl maleate is especially preferred. See instant claim 37. The copolymer of instant claim 39 is taught in Example 2. The reference teaches that the film-formers can be mixed with cellulose nitrate (which is used in the Revlon nail polish composition). See col. 4, lines18-23. The reference also teaches the additives that are commonly used in nail lacquer art, which include 2-hydroxy-4-methoxybenzophenone, ammonium sulfite, esters and salts of thioglycolic acid, urea, allantoin, enzymes, and salicylic acid. See col. 4, line 50 – col. 5, line 24. See instant claims 46 and 47.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Bernstein by adopting the nail lacquer

formulation of Bohn, as motivated by the latter reference, because both references are directed to nail lacquer compositions for treating antifungal infections. The skilled artisan would have had a reasonable expectation of successfully producing an anti-psoriasis nail lacquer composition with similar occlusive effects.

Response to Arguments

Applicant's arguments filed on August 2, 2006 have been fully considered but they are moot in view of new grounds of rejection in part, and not persuasive in part.

Applicants' argue Bernstein "teaches away" from employing clobetasol propionate, which is said to be more potent than Valisone (the betamethasone valerate composition of Bernstein). The argument is not persuasive because Fredriksson teaches that betamethasone and valerate clobetasol betamethasone are interchangeable for the same purposes.

Applicants have submitted non-prior art references as evidence to support the position that betamethasone valerate, which is used in the Bernstein invention, is a mid-strength steroid as compared to clobetasol propionate. These references will not be considered in the present examination because these could not have affected the motivation of the skilled artisan, as the references were not available at the time of the present invention.

Applicants also argue that Fredriksson, which was cited in the previous rejection, requires a combination of a corticosteroid and an antifungal agent other than corticosteroid. As indicated in Response to Arguments in previous Office actions, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The idea of using steroidal glucocorticoid alone as the sole antifungal agent in a nail varnish formulation to treat psoriasis of nails is already well known in the art, as evidenced by Bernstein.

Applicants also argue that corticosteroid in Fredriksson is used merely to suppress the skin irritation and inflammation caused by the antifungal agent. Examiner respectfully disagrees, since Fredriksson also illustrates a method of treating psoriasis with corticosteroid alone. See col. 3, line 1- col. 4, line 10. It is well settled in patent law that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." See In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Although the effectiveness of 0.025 and 0.1 % of corticosteroid was less as compared to 1 % of 5-fluorouracil, the reference nonetheless teaches the use of corticosteroid alone as an anti-psoriasis agent. Bernstein also teaches that a nail polish with a glucocorticoid alone as an active ingredient has been used to treat nail psoriasis. Thus, applicants' arguments are viewed unpersuasive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina C. Yu
Patent Examiner
9/30/06